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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,743	01/23/2002	Paul Miller	S63.2-9964	7373

490 7590 06/27/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

NOLAN, SANDRA M

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 06/27/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,743

Applicant(s)

MILLER ET AL

Examiner

Sandra M. Nolan

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 + 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claims

1. Claims 1-25 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13 and 23-25, drawn to devices, classified in class 428, subclass 36.91.
 - II. Claims 14-22, drawn to methods of making devices, classified in class 156, subclass (unknown).
3. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by coextruding its three layers.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Ms. Lisa Ryan-Lindquist on 23 June 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13 and 23-25.

5. Affirmation of this election must be made by applicant in replying to this Office action.

6. Claims 14-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

8. The information disclosure statements (IDS) submitted on 07 May 2002 (Paper No. 2) and 21 April 2003 (Paper No. 3) were considered by the examiner.

Claim Objections

9. Claim 17 is objected to because of the following informalities: the term "copolymers" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 4, 5, 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What does "coextensive along at least a portion of the length" (claims 4 and 5) mean? What does "maleated" (claims 12 and 19) mean?

Please clarify the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 4, 5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuelson et al (US 6,165,166).

Samuelson teaches trilayer medical tubing (title) for catheters (col. 1, line 20). The outer layer of the tubing contains a polyether block polyamide (col. 6, line 19), the inner layer contains high density polyethylene (col. 6, line 44), and the intermediate tie layer (col. 6, line 55) joins the inner and outer layers. The tie layer contains a maleic acid modified olefinic material (col. 7, lines 31-43). As shown in Figures 4 and 7, the tubing sections are coextensive in some places and non-coextensive in others.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson.

Samuelson is discussed above.

It fails to teach butt and lap joints between tubular members.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ butt or lap joints in the production of catheters from the trilayer tubing of Samuelson.

In the absence of convincing objective evidence to the contrary, the production of catheters using butt or lap joints is deemed a matter of engineering choice, depending upon the sections of the catheters to be bonded.

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17. Claims 3, 13 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson as applied to claims 1, 2, 4, 5 and 8-12 above, and further in view of Graham et al (US 4,602,058).

Samuelson is discussed above. Note that, at col. 4, lines 33-37, it teaches that the intermediate layer contain a material containing functionality to make it capable of adhering to both the outer and inner ("core") layers.

It fails to teach the use of blends of polyamides and polyethylenes, or polymers compatible therewith, in tie layers for its trilayer tubing.

Graham teaches that blends of polyamides (col. 1, lines 17-31) and polyolefins based on polyethylene (col. 1, line 64 through col. 2, line 3) in bonding layers for laminates (col. 12, lines 60-67).

The patents are analogous because they both deal with multilayer structures.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the polyamide/polyolefin bonding materials of Graham as tie layers for the catheters of Samuelson in order to effect bonding between the polyamide- and polyolefin-containing layers thereof.

The motivation to employ the blends of Graham as the tie layers in the catheters of Samuelson is found at col. 12, lines 60-67 of Graham and at col. 4, lines 33-37 of Samuelson, where the use of the materials that form interlayer bonds is suggested by both.

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It is deemed desirable to make catheters using tie layers that promote interlayer adhesion between the outer and inner layers thereof in order to minimize the possibility of delamination of the catheters.

Conclusion

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The fax number for after final communications is 703/872-9310. The receptionist answers 703/308-0661.



S. M. Nolan
Patent Examiner
Technology Center 1700

SMN/smn
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